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ABSTRACT

Strain shielding, a mechanical effect occurring in structures combining stiff with more flexible materials, is considered to lead to a reduction in bone density in bone surrounding the implant and be related with weakness of the implant fixation, which leads to implant loosening. Several studies describe a significant decrease in postoperative bone mineral density adjacent to the joint implants, which can compromise their fixation at long term. Therefore the aim of the present study was the quantification of the strain shielding effect on the distal femur after patellofemoral arthroplasty. For this purpose three activities of daily living were considered: level walking, climbing stairs and deep bending at different angles of knee flexion. To determine the strain shielding effect, cortical bone strains were measured experimentally with tri-axial strain gauges in synthetic femurs before and after patellofemoral arthroplasty for the different daily activities. The results showed that the patellofemoral arthroplasty in general reduced the strains in the medial and distal regions of the femur for the deep bending activity occurring, consequently strain shielding effect in these regions, strain decreases of -72.0% and -67.5 % were measured. On the other side, higher values of strain were found in the anterior region after patellofemoral replacement for this activity with an increase of +182.0%. The occurrence of strain shielding looks more important when the angle of knee flexion and applied load increase. The strain shielding and over-loading may have relevant effects on bone remodeling surrounding the patellofemoral implant, suggesting a potential effect of later bone resorption in the medial and distal femur regions in case of a great frequency of the deep bending activity.

KeyWords: patellofemoral arthroplasty, strain shielding, experimental strains.

25 INTRODUCTION

26 The patella is of special interest to the medical profession since it is a highly injurable
27 mechanism. It experiences loads higher than those in the tibiofemoral (TF) joint in some
28 orientations (Amis and Farahmand, 1996) and, despite having the thickest articular
29 cartilage in the body, it is still one of the most degenerative joints (Minns and Stevens,
30 1977). The patellofemoral (PF) joint belongs to the extensor mechanism of the knee
31 where the patella can be considered as the largest sesamoid bone improving the
32 effective extension capacity of the quadriceps muscle (Tecklenburg et al., 2006) by
33 increasing the moment arm of the quadriceps muscle force to the center of rotation of
34 the knee. The patella also allows a better distribution of the reaction force on the femur
35 by increasing the area of contact (Reilly and Martens, 1972). Besides, according to
36 some authors (Fick, 1904; Freehafer, 1962) it provides the anterior aspect of the knee
37 with a protecting shield.

38 Many times, patients with a knee arthritis affecting only the PF joint were found. For its
39 treatment a wide variety of techniques, from conservative treatment with physiotherapy,
40 anti-inflammatory drugs, synovial fluid replacement or cartilage nutrients has been
41 proposed (Vázquez and Mejorado, 2005). In most patients with a painful knee, caused
42 by patellar chondromalacia or patellofemoral arthrosis, a simple conservative treatment
43 is effective since this kind of pathology, looks relatively well tolerated. But there are a
44 few patients, who do not respond, or respond inadequately, to conservative treatment.
45 The radical solution to the problem is excision of the patella (patellectomy). However,
46 this operation has disadvantages leading to decreased quadriceps power and subsequent
47 quadriceps atrophy and loss of extensor force generated by the knee with the subsequent
48 weakness, persistent pain and instability in some patients (Fernandez and Hunter, 2005).

Prosthetic replacement of the articular surface of the patella is an alternative, which has not been widely studied (Arnbjörnsson and Ryd, 1998; Vázquez and Mejorado, 2005). Patellofemoral arthroplasty was first described in the mid 50's by McKeever (1955) followed by DePalma et al. 1960 (Arnbjörnsson and Ryd, 1998) and its materials, designs, surgical procedures and results have been improved since then, even though this kind of treatment is still not widely accepted (Vázquez and Mejorado, 2005). Typical failure mechanisms of patellofemoral arthroplasty include patellar maltracking and progressive femorotibial arthritis. Failure, wear and loosening of the trochlear component have been reported (Arciero et al., 1988; Argenson et al., 2005; Blazina et al., 1979; Board et al., 2004; Cartier et al., 1990; Cartier et al., 2005; de Winter et al., 2001; Feller et al., 1993; Kooijman, 2003; Krajca-Radcliffe et al., 1996; Leadbetter et al., 2008; Lonner, 2004; Lubinus, 1979; Simth et al. 2002; Tauro et al., 2001). The implant-related bone loss occurs mainly as a result of strain shielding and wear, increasing the risk of periprosthetic fracture or weakness of the implant fixation, which leads to implant loosening (Van Loon et al., 1999). Several studies describe a significant decrease in postoperative bone mineral density, adjacent to the implants, after arthroplasty (Li and Nilsson, 2000; Soininvaara et al., 2004). Strain shielding is a mechanical effect occurring in structures combining stiff with more flexible materials. Bones in normal, healthy conditions carry external joint and muscular loads by themselves. Following the insertion of orthopaedic implants, the treated bone will share its load-carrying capacity with it. Thus the same load that had been originally born by the bone itself will now be carried by the 'composite' new structure (Gefen, 2002). Consequently the bone surrounding the implant alters its natural remodeling process and adjusts its mineral density and structure. Even though the mechanism of bone

remodeling is still subject of controversy, most theories assume strain-based criteria (Frost 1969; Schaffler et al., 1990, Yeh and Keaveny, 2001).

The aim of this study was the quantification of the strain shielding effect on the distal femur following patellofemoral arthroplasty. For this purpose, three activities of daily living were considered: level walking, climbing stairs and deep bending at different angles of knee flexion. To determine the strain shielding effect, cortical bone strains were measured experimentally with tri-axial strain gauges in synthetic femurs before and after *in vitro* patellofemoral surgery for the different daily activities. The main motivation for this evaluation was to understand the mechanical effects occurred by the patellofemoral replacement in order to improve its performance later by changing its characteristics, implicating a better adaptation of the patients to the prosthesis and consequently increasing their quality of life.

MATERIALS AND METHODS

Five synthetic femurs (model 3406), one of them can be seen in Figure 1 (below) (before and after *in vitro* surgery), and one tibia (model 3402) from Sawbones® (Pacific Research Lab, Inc., Vashon Island, WA, USA) were selected and used for this experimental study. The geometrical and anatomical structure of these synthetic composite bones resembles that of humans. Previous studies (Heiner and Brown, 2001 and 2003) have shown that axial, bending and torsional stiffness of the composite and strain distribution in the femur are similar to those occurring in natural human bones. Moreover, this femur model was chosen to minimize the high inter-specimen variability in mechanical properties often associated with the use of cadaveric bones in experimental biomechanical analyses (Heiner, 2003).

Patellofemoral articulation prosthesis (patellofemoral arthroplasty) from Smith & Nephew, Inc. (Memphis, TN, USA) was used. The implant, shown in Figure 2A and 2B, is composed of Oxinium, created from a compound of 97.5% zirconium and 2.5% niobium. The Oxinium material is a metal with the surface transformed into a ceramic. Oxygen diffuses into zirconium creating a 5-micron thick ceramic surface, as it is possible to observe in Figure 2C, and leaving a metal core to retain strength and flexibility. Implanted under the patella is the Ultra-High Molecular Weight Polyethylene (UHMWPE) patellar prosthetic component, shown in Figure 2D. The patellofemoral replacement surgery was made into the intact femur by an experienced surgeon. The *in vitro* insertion procedure was performed according to the protocol described for this type of patellofemoral prosthesis.

Triaxial (rosette) strain gauges (KFG-3-120-D17-11L3M2S, Kyowa Electronic Instruments Co., Ltd., Japan) were glued in native femur at the five anatomical locations those can be seen in Figure 1: two gauges onto the distal region (medial and lateral superior sides), one on the anterior side surface and the other ones were placed on lateral, medial side of the condyles surface. All strain gauges were connected to a data acquisition system PXI-1050 from National Instruments (Texas, United States), which was connected to a PC to record the data by using NI LabView SignalExpress Software.

Quadriceps muscle force and knee flexion influence the patellofemoral joint reaction force by changing the angle between the patellar tendon and the quadriceps tendon. In other words, for different flexion angles at different activities there is a respective patellofemoral joint reaction force. For this purpose each one of the five specimens was assembled on the platform of the testing machine fixing the femur and tibia diaphysis through stiff metal parts (Figure 3). This configuration allows a contact of femur and

tibia by their condylar surfaces and, at the same time, leaves the femur patellar region free to a load application. At each test, the femur and tibia were angularly positioned in order to simulate the knee at 12°, 50° and 90° of flexion. With the purpose of simulating the patellofemoral joint reaction force (PJRF), a vertical load was applied on the trochlear region of the native femur (before surgery) or on the patellofemoral prosthesis of the implanted femur (after surgery), through a customized construct of the prosthetic patellar component (Figure 3). Each angle encounters a different contact location between femur and patella being there where the respective loads were applied. The different values of forces (applied loads), contact surfaces locations and flexion angles were based on the work of Donald Reilly (1972) and J. W. Fernandez (2005), respectively. This load corresponds to patellofemoral joint reaction force during various activities of daily living at different angles of knee flexion. All the studied situations and corresponding applied loads and angles are listed in the Table 1. Despite the loading machine apply only one force to the femur at the patellar region, the contact between the femur and the tibia by their condylar surfaces at one flexion angle generates also a tibiofemoral reaction force. The value of tibiofemoral force is directly related with the patellofemoral force by the angle of knee flexion. This means that the distal femur was subjected simultaneously to both patellofemoral and tibiofemoral reaction forces, what is very close to the physiological load condition.

Bone strains were obtained for three load cases (Table 1) before and after surgery: Load case 1 represents the level walking activity with 12° of knee flexion where the patellofemoral reaction force (PRF) is equal to 143N; load case 2 represents the climbing stairs with 50° of knee flexion where the PRF is equal to 2500N; and, load case 3 pertain to deep knee bending with 90° of knee flexion where the PRF is equal to

2440N. Before applying the previously mentioned loads, each specimen was preconditioned with a force of 40N acting during 1 minute, followed by a 4 minutes relaxation phase. Immediately following relaxation, each specimen was subjected to different loads as described above. A total of five tests were performed for each situation of activity and angle, each one for each femur. All previous experimental procedures made for intact model were repeated for implanted model (after *in vitro* surgery). The model used as intact was also used like implanted in order to eliminate the probable variability of the strains obtained caused by the difficulty in accurately placing the strain gauges in the same positions of the two different specimens.

The maximal (ϵ_1) and minimal (ϵ_2) principal strains within the plane of the gauge were calculated for all positions and averaged over the remaining reconstructions for each gauge location, and standard deviations were determined. The strain shielding effect was presented by the magnitudes and percentages difference between principal strains, in each gauge position of the implanted femur relative to the intact femur. The negative values express a reduction relatively to the intact femur and the positive ones an increase.

RESULTS

The standard deviation for the measured principal strains obtained from the ten loading assay was smaller than 10% of the respective mean of principal strains for each gauge position and can be depicted in Table 2 for the load case 2. The mean of principal strains and their standard deviations of implanted and intact femur are presented in Figure 4 for the three load cases. The magnitude and percentages of change for each

principal strain when compared with the intact situation are presented in Table 3 for all three load cases.

For load case 1, all positions increased the magnitude of minimal principal strains (ϵ_2) relatively to the intact situation, except the anterior side (A) where there was a decrease with -36.8% (-21×10^{-6} m/m). The highest nominal increase was originated in the medial superior side (MS) with +71.8% ($+31 \times 10^{-6}$ m/m) for the minimal principal strains. Similarly, there was a dominance of the magnitude increases after surgery in terms of maximal principal strains (ϵ_1). All positions increased the nominal maximal principal strains relatively to the intact situation, except the lateral side (L) where there was a slight nominal reduction. The biggest nominal increase occurred in the anterior side (A) with +44.7% ($+16 \times 10^{-6}$ m/m) for the maximal principal strains.

For load case 2, two femur regions (medial and lateral sides) decreased the magnitudes of minimal principal strains while the other positions increased them after implantation. The greatest nominal increase occurred in the lateral superior side (LS) +208.8% ($+271 \times 10^{-6}$ m/m) and the biggest nominal reduction was observed in the medial side (M) with -60.1% (-330×10^{-6} m/m) for the minimal principal strains. An increase of nominal maximal principal strains relatively to the intact situation occurred in all positions, except in the anterior side (A) where there was a reduction with -141.5% (-177×10^{-6} m/m). Opposite to what happened in minimal principal strain (ϵ_2), the greatest nominal increase occurred in the medial side (M) with +210% ($+252 \times 10^{-6}$ m/m).

For load case 3, all positions studied on the femur decreased the magnitudes of minimal principal strains relatively to the intact situation, except the anterior (A) and lateral sides (L). A similar result was found for maximal principal strain, where the only side that

increased its strain after implantation was the lateral side (L). The highest nominal increase was observed in the anterior side (A) with +182% ($+701 \times 10^{-6}$ m/m) and the greatest reduction of nominal minimal principal strain occurred in lateral superior side (LS) with -67.5% (-942×10^{-6} m/m). The only increase observed in terms of maximal principal strain reached at the lateral side (L) with +65.6% ($+127 \times 10^{-6}$ m/m) and the highest nominal reduction was found in lateral superior (LS) side with -43.5% (-707×10^{-6} m/m).

In order to evaluate the linearity response of the different experimental models the linear regressions between the principal strains and applied loads were calculated for all three activities. The linear regression analysis showed that for all locations of the gauges, the correlation coefficient (R) presented values near or, in some cases, even equal to 1, having been especially high in the medial (M) and lateral superior (LS) for both principal strains. In Figure 5 can be depicted the linear regression for a 12° knee flexion at the lateral superior (LS) gauge position.

DISCUSSION

The purpose of this study was to evaluate experimentally strain shielding in the distal femur with three different angles of knee flexion for three activities of daily living, caused by patellofemoral replacement, by comparing cortical strains between the implanted and intact femur. Several experimental studies with composite bones were carried out involving the measurement of bone surface strains, with the main purpose of responding to a clinical need to investigate *in vitro* implant-bone load transfer mechanisms, monitoring the strain shielding effect and for finite element model validation (Completo et al., 2007; Completo et al., 2008a; Waide et al., 2003; Viceconti

el al., 2001, Cristofolini et al., 1996). The standard deviations of principal strains obtained in this study were in range of those calculated in the other experimental studies with synthetic femurs, e.g. Completo et al., 2008a; Completo et al., 2008b; Waide et al., 2003; Viceconti et al., 2001; Cristofolini et al., 1996.

Overall the magnitudes of minimal principal strains were higher than the magnitudes of maximal principal strains in most of strain gauges. Also the nominal strain changes between implanted and intact femur were greater for minimal principal strains than for maximal principal strains in most of strain gauges. Due to this fact, special attention was given to the changes of minimal principal strains. Furthermore, the lowest strain magnitudes and the lowest strains changes occurred for the level walking activity (load case 1) for both minimal and maximal principal strains, showing values of strain changes below $31 \times 10^{-6} \text{m/m}$. Therefore, the load case 1 can be considered negligible when compared with the strain changes occurred in the other two load cases and a closer attention was given to these two activities.

The strain changes occurring after any bone replacement can disturb the normal remodeling process of the physiological bone, resulting in a change of its capacity to maintain the density and consequently its strength surrounding the implant (Frost, 2004). Thus the underloading (strain shielding) can promote an early reduction of the bone density and, possibly bone resorption and then contribute to failure of the implant support. The overloading, on the other side, can promote formation of bone causing a localized increase of bone density or even inducing fatigue damage, when the increases of strains exceed the fatigue strength of the host bone (Frost 2004). For instance, Turner et al., 1997, showed that the average amount of femoral bone loss in a dog model was

related to implant stiffness and attributed this effect to the greater degree of periprosthetic bone stress shielding engendered by the stiffer implant.

Based on the resulting strains obtained within this experimental study and extrapolating them for physiological conditions, it is possible to predict potential effects of strain changes in the bone remodeling process of the femur surrounding the implant after patellofemoral replacement. Looking carefully at the studied regions, we may reach at the conclusion that some of them were more susceptible to strain changes after patellofemoral replacement than others for the different daily activities analyzed. The region where the lowest strain changes occurred was the lateral (L). Thus, we can suppose that the patellofemoral replacement does probably not alter the normal bone remodeling process in this region for almost all daily activities analyzed. In the anterior (A) region, the magnitude of minimal principal strains after patellofemoral replacement were in general bigger than those which happened for the intact situation, particularly at the biggest knee flexion angle. This strain increase may put the risk of bone resorption out in this zone after surgery, although there is a good chance that the risk of bone fatigue damage may be increased in case of an intense deep bending activity. In the most distal regions on the femur (LS and MS), the strain changes between before and after patellofemoral replacement were very dependent on the daily activity analyzed. For the level walking and climbing stairs activities a general increase of both minimal and maximal principal strains was observed after *in vitro* surgery. An opposite effect occurred for the deep bending activity with an outstanding strain reduction in lateral region (LS) after replacement. Because the high magnitudes of the strain changes occurred by strain shielding in this region, the bone resorption may well happen for an intense deep bending activity. In the medial (M) region the greatest reduction of the

minimal principal strains after patellofemoral replacement occurred especially for the deep bending activity, which can promote a later bone resorption effect. An overall view of these results showed that the increase of knee flexion increased the bone regions subjected to strain shielding effect, meaning that a high frequency of deep bending activity should be avoided after patellofemoral replacement because of the increased risk of bone resorption in the long-term.

To date, and according to the authors' knowledge there are no published biomechanical or clinical studies examining the strain shielding effect or even changes in bone mineral density after patellofemoral arthroplasty, therefore the comparative discussion was limited. However, some retrospective studies analyzing clinical outcomes after patellofemoral arthroplasty at different follow-up were regarded. In addition to the previous mentioned failures, early-generation implants in particular, had a relatively high tendency for failures related directly to patellar maltracking (Arciero et al., 1988; Board et al., 2004; Lonner et al., 2004; Tauro et al., 2001; Smith et al., 2002). Hendrix et al. (2008) did a revision study of these outcomes and concluded that, although many of these failures have been attributed to component malposition or soft tissue imbalance, the likelihood is that many of these were in fact hastened by particular design features of the trochlear components, which put the patella at risk of catching, snapping, and subluxation on its proximal and lateral edges. In 2007 Ackroyd, Newman and coworkers analyzed the results of their Avon prosthesis in 85 patients followed for at least 5 years. The 5-year survivorship was 96%, and the main complication was radiographic progression of arthritis in the other compartments, which was noticed in 25 patients. No clinical observations about using the Journey patellofemoral prosthesis from Smith & Nephew have been reported, giving notice to this study. In none of these

mentioned clinical studies was bone loss or any signal of osteopenia in the femur surrounding the patellofemoral prosthesis referred. This fact does not assert the opposite of what happen on our tests. Our outcomes only demonstrated a pronounced effect of strain shielding for the deep bending activity, which is not a common daily activity. For the most repeated daily activities like walking and climbing stairs, our results did not manifest an important reduction of the strains after patellofemoral arthroplasty.

This study presented some limitations. The knee is assumed to be statically loaded. *In vivo*, the motions of the knee are controlled by imposed forces, either directly by the joint reaction force or indirectly via the restraints of the surrounding soft tissues, namely the ligaments. Only the patellofemoral reaction force was taken into account without consideration for either quadriceps force or patella ligament force, although those three main forces are related by the knee flexion angle. Moreover, the results were limited to the patellofemoral prosthesis design, meaning that other designs/materials may generate magnitudes different from those obtained from this study and for this reason a comparison between different designs would just be speculative. Therefore, due to the comparative nature of the study, where different load cases were compared between themselves, the results are representative of major differences between the two models analyzed.

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Figure 1 – Femur with positions of each strain gauge. **A.** The bone strains were measured from 2 gauges glued on the anterior side (A1 and A2) and 4 gauges glued on the medial (M1 and M2) and lateral (L1 and L2) sides and 4 gauges glued on the medial (SM1 and SM2) and lateral (SL1 and SL2) sides in the distal end of the femur. **B.** Triaxial strain gauges placed on the native (on left) and implanted femur (on right).

Figure 2 – Journey patellofemoral joint implant from Smith & Nephew. **(a)** Anterior and **(b)** posterior views of the femoral component. Note that the implant is broad and asymmetric to help capture the patella and aid tracking. **(c)** Oxinium sphere showing its composition from the core until surface. **(d)** UHMWPE patellar component of the prosthesis (adapted from Smith & Nephew, 2008).

Figure 3 – Picture of the loading machine with the specimen in the test position.

Figure 4 – Mean and standard deviation of the minimal (ϵ_2) and maximal (ϵ_1) principal strains of the implanted and intact models for Load case 1, Load case 2 and Load case 3 in the Anterior (A), Medial (M), Lateral (L), Medial Superior (MS) and Lateral Superior (LS) sides.

Figure 5 – Linear regression of native (left) and implanted (right) patellofemoral joint with respect to minimal and maximal principal strains for a 12° knee flexion angle to different activities at the lateral superior (LS) gauge position.

Table 1

ACTIVITY	FLEXION ANGLE		
	12°	50°	90°
Load Case 1			
Level walking	143N	-	-
Load Case 2			
Climbing stairs	192N	2500 N	-
Load Case 3			
Deep knee bending	220N	720 N	2440 N

Table 2

Mean and standard deviation of minimal (ϵ_2) and maximal (ϵ_1) principal strains for load case 2

Strain gauge	A			L			LS			MS			M		
	Mean	Sdev	Sdev/mean	Mean	Sdev	Sdev/mean	Mean	Sdev	Sdev/mean	Mean	Sdev	Sdev/mean	Mean	Sdev	Sdev/mean
	(10 ⁻⁶ m/m)	(10 ⁻⁶ m/m)	%	(10 ⁻⁶ m/m)	(10 ⁻⁶ m/m)	%	(10 ⁻⁶ m/m)	(10 ⁻⁶ m/m)	%	(10 ⁻⁶ m/m)	(10 ⁻⁶ m/m)	%	(10 ⁻⁶ m/m)	(10 ⁻⁶ m/m)	%
Intact															
ϵ_1	125	9,6	7,7	224	1,3	0,6	709	7,8	1,1	400	3,4	0,9	-120	8,9	-7,4
ϵ_2	-220	2,5	1,1	-405	5,6	1,4	-130	2,0	1,6	-330	6,7	2,0	-548	18,3	-3,3
Implanted															
ϵ_1	-52	4,7	9,1	230	3,2	1,4	768	5,7	0,7	518	14,9	2,9	132	1,4	1,0
ϵ_2	-297	1,3	0,4	-313	9,3	3,0	-400	1,8	0,4	-492	4,2	0,8	-219	2,2	-1,0

Table 3

Magnitude and percentage changes of principal strains between implanted and intact femur

Strain gauge position		Anterior (A)		Medial (M)		Lateral (L)		Medial Superior (MS)		Lateral Superior (LS)	
		(10 ⁻⁶ m/m)	(%)	(10 ⁻⁶ m/m)	(%)	(10 ⁻⁶ m/m)	(%)	(10 ⁻⁶ m/m)	(%)	(10 ⁻⁶ m/m)	(%)
ϵ_1	Load case 1	+16	+44,7	+14	+24,7	-2	-6,5	+3	+7,5	+6	+11,5
	Load case 2	-177	-141,5	+252	+210,3	+6	+2,4	+117	+29,3	+60	+8,4
	Load case 3	-111	-37,6	-179	-57,9	+127	+65,6	-245	-28,7	-707	-43,5
ϵ_2	Load case 1	-21	-36,8	+13	+20,2	+0,1	+0,63	+31	+71,8	+12	+27,2
	Load case 2	+77	+35,2	-330	-60,1	-92	-22,8	+162	+49,0	+271	+208,8
	Load case 3	+701	+182,0	-657	-72,0	34	+6,6	-69	-15,7	-942	-67,5

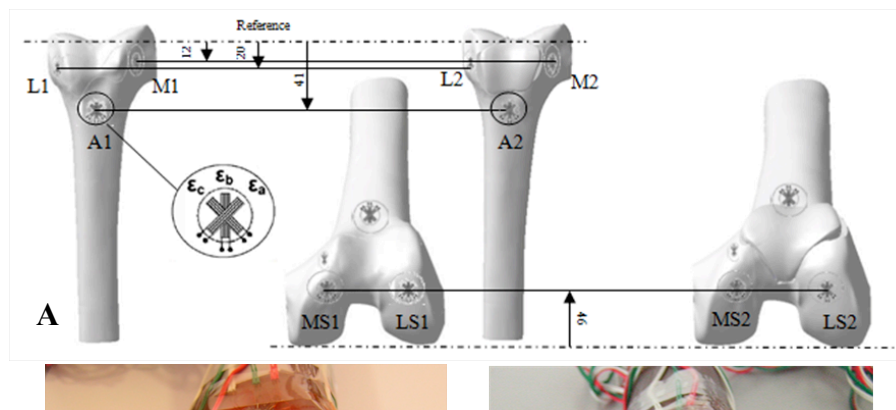


Figure 1

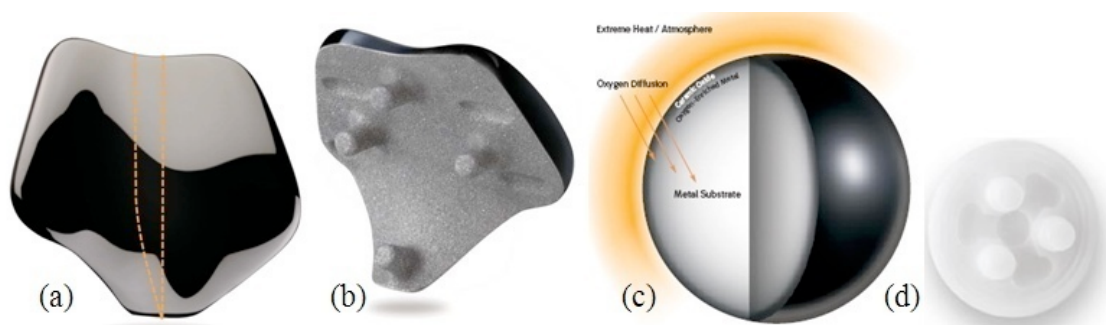


Figure 2

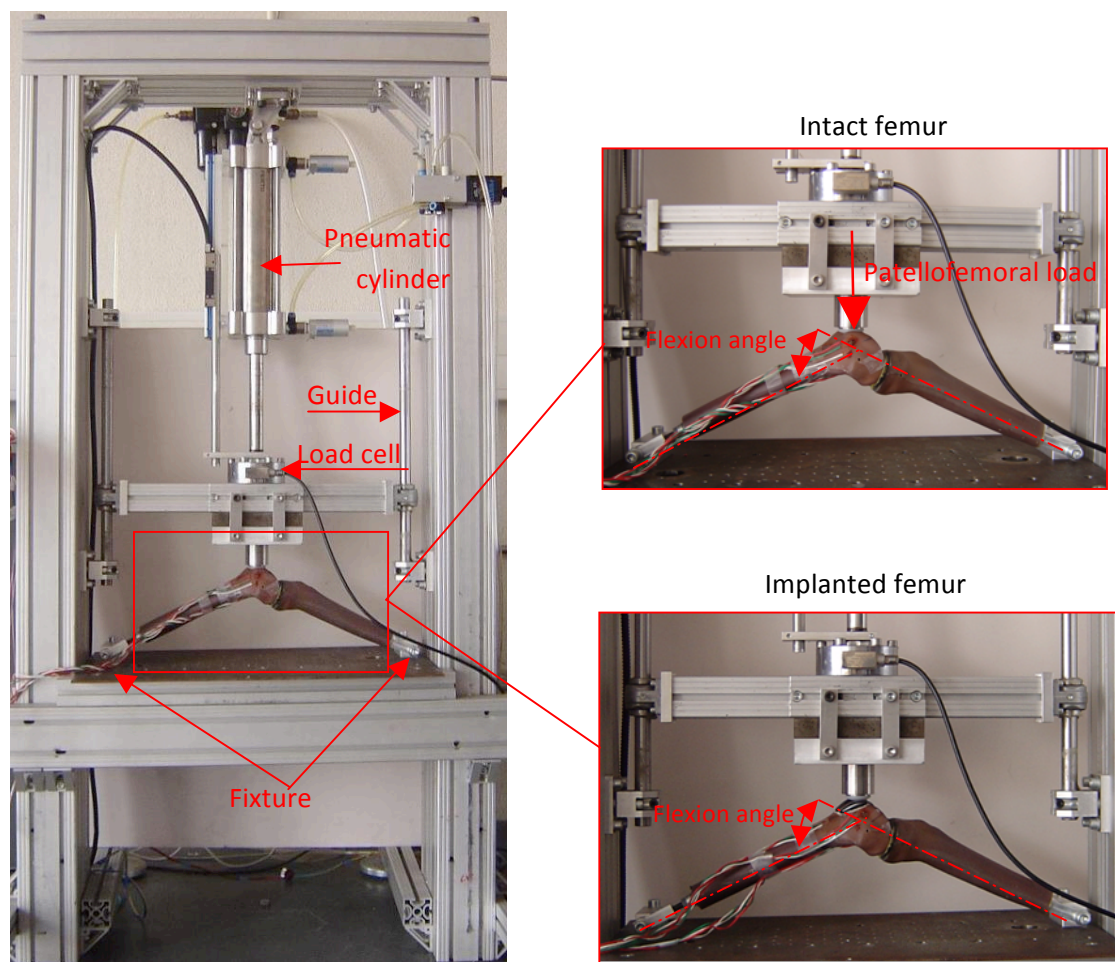


Figure 3

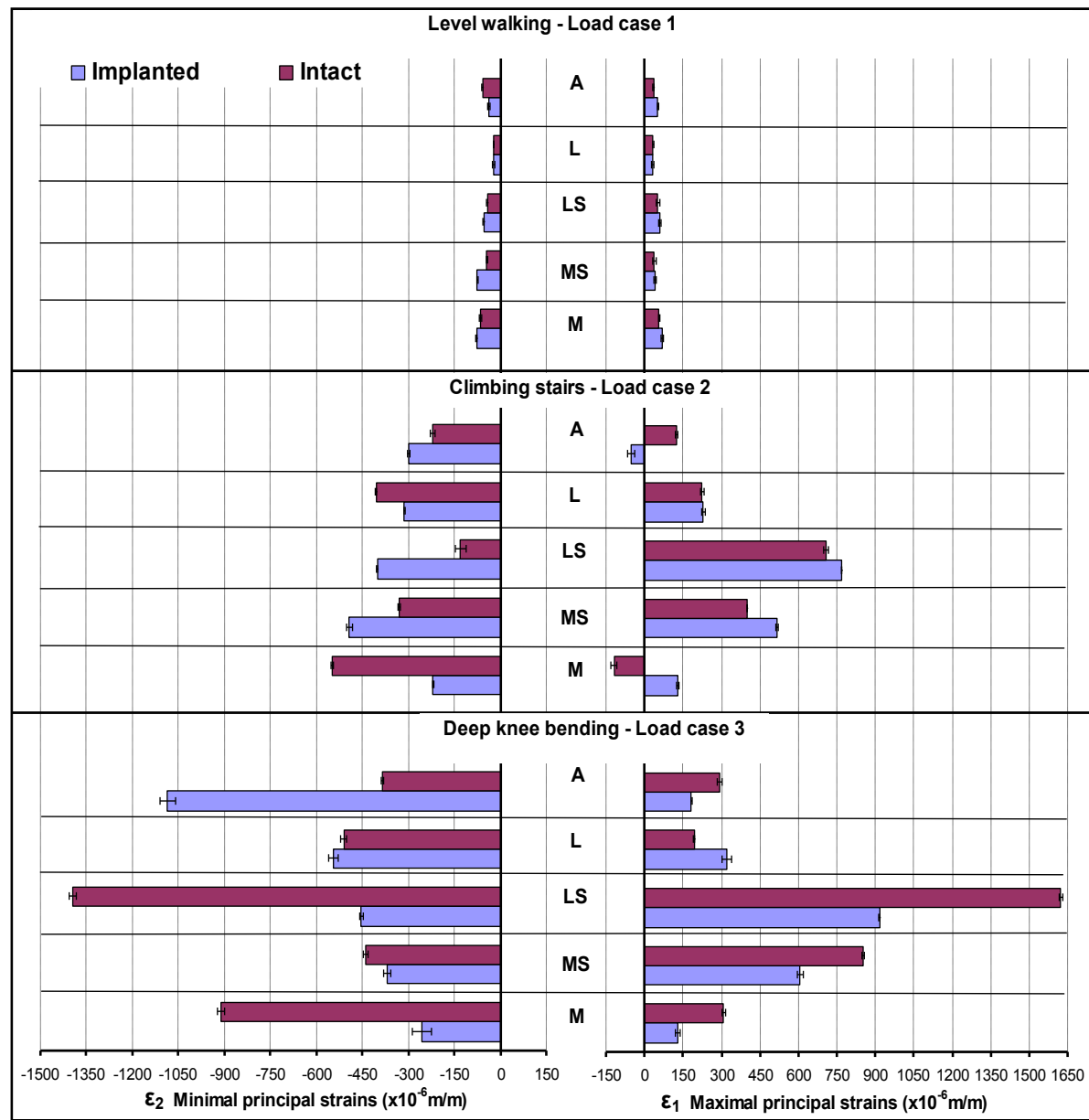


Figure 4

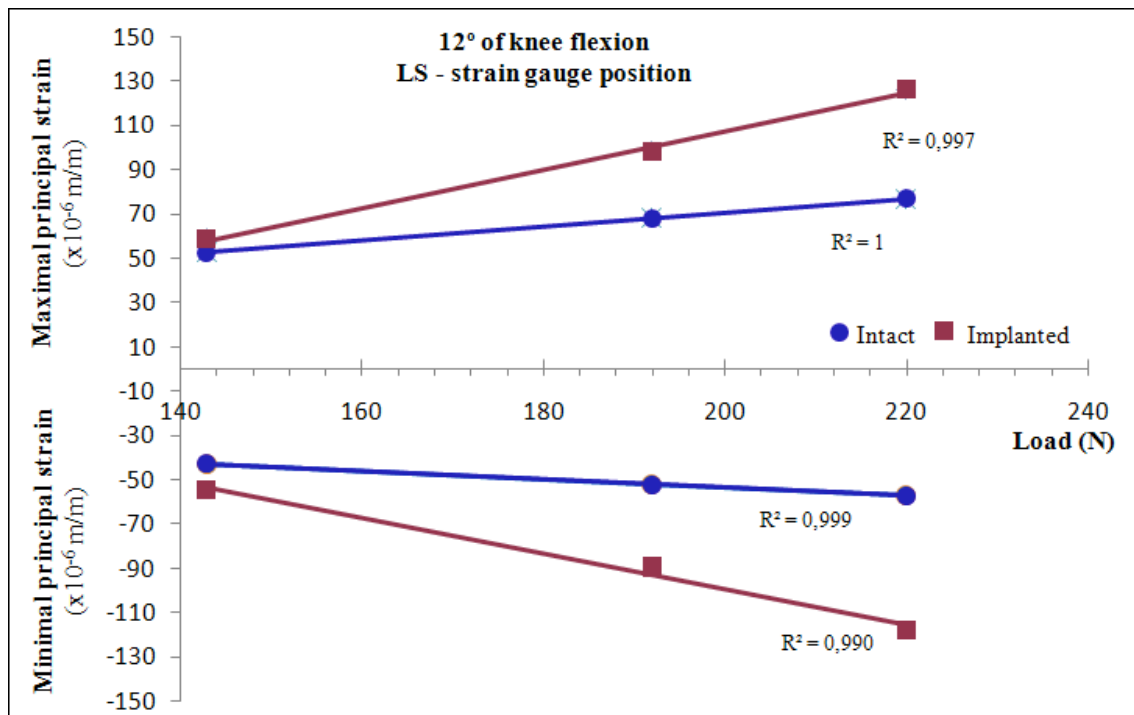


Figure 5